IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S Plaintiff, v. ACAMBIS INC., and ACAMBIS, PLC Defendants.	Civ. Action No._____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Bavarian Nordic A/S ("Bavarian Nordic"), by its attorneys, hereby demands a trial by jury on all issues so triable and complains against Defendants Acambis Inc. and Acambis Plc (collectively "Acambis"), as follows:

NATURE OF CASE

1. Bavarian Nordic seeks injunctive relief, return of proprietary material, and damages for acts of unfair competition, conversion, and misappropriation of trade secrets, engaged in by Defendants in violation of the laws of the United States and the State of Delaware.

JURISDICTION

2. This Court has jurisdiction over the common law and state law claims under 28 U.S.C. § 1332, as this is a matter involving claims between parties whose citizenship is diverse, and the amount in controversy, exclusive of interest and costs, exceeds seventy-five thousand dollars ($75,000), and pursuant to 15 U.S.C. § 1121, which grants to federal district

courts original jurisdiction over all actions arising under the Lanham Act, and 28 U.S.C. § 1338 and 1367, as at least part of Bavarian Nordic's claims are predicated on the Trademark Act of 1946, as amended, 15 U.S.C. § 1051, *et seq.*, and related claims under the common law of the State of Delaware.

3. Venue lies in the District of Delaware pursuant to 28 U.S.C. § 1391 because Defendants are subject to personal jurisdiction in the State of Delaware and therefore are deemed to reside in this judicial district and because Acambis Plc is an alien for which venue is proper in any judicial district in the United States.

THE PARTIES

4. Bavarian Nordic is a corporation duly organized and existing under the laws of the nation of Denmark, and maintains its principal place of business at Bøgeskovvej 9, DK-3490 Kvistgård, Denmark. Bavarian Nordic is the owner of the proprietary information and material which is at issue in this action.

5. Upon information and belief, Defendant Acambis Inc. is a corporation duly organized and existing under the laws of the State of Delaware, with a registered address of Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801 in the county of New Castle. Acambis Inc. does and/or conducts business activities, including those complained of herein, in the State of Delaware. Acambis Inc. may be served in this District through its registered agent, The Corporation Trust Company, also of Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

6. Defendant Acambis Plc is a corporation organized and existing under the laws of the nation of the United Kingdom, with a registered address of Peterhouse Technology

Park, 100 Fulbourn Road, Cambridge CB1 9PT, UK. Acambis Plc does and/or conducts business activities, including those complained of herein, in the State of Delaware. The company secretary is Elizabeth Brown, also of Peterhouse Technology Park, 100 Fulbourn Road, Cambridge CB1 9PT, UK.

7. Upon information and belief, Acambis Inc. is the alter ego of Acambis Plc, and both Acambis entities share research personnel and jointly market vaccine products to U.S. customers, including agencies of the U.S. government.

FACTUAL BACKGROUND

SMALLPOX AND SMALLPOX VACCINES

8. Smallpox is an acute contagious disease usually spread from person to person through close contact. One form of the disease, variola major, is highly virulent with a mortality rate of greater than 30 percent. While there is no specific treatment for smallpox, it can be prevented through vaccines.

9. The only smallpox vaccine approved by the FDA for innoculating the general population in the United States is Dryvax®, which is a live-virus preparation of vaccinia virus prepared from calf lymph. The calf lymph is purified, concentrated, and dried by a process called lyophilization. There are several other smallpox vaccines currently being evaluated in clinical investigations that are derived from the same virus strain as Dryvax®.

BAVARIAN NORDIC'S BREAKTHROUGH VACCINE

10. Bavarian Nordic is a world leader in the development and production of innovative vaccines and related products which prevent and treat infectious diseases.

11. Beginning in 1996, Bavarian Nordic sought to develop a new generation of smallpox vaccines that would be safer and more effective for individuals for whom the traditional smallpox vaccine is more dangerous, such as patients with disorders of the immune system, skin conditions such as eczema, or other disorders presenting a high risk of complications from existing smallpox vaccines. Through an extensive, multi-million dollar research and development effort, Bavarian Nordic developed such a smallpox vaccine based on Bavarian Nordic's core technology, MVA-BN®.

12. MVA-BN® is a strain of modified vaccinia virus Ankara ("MVA") that cannot replicate inside human cells. Therefore, MVA-BN® is one of the world's safest multivalent vaccine vectors for the development of vaccines against smallpox, as well as HIV/AIDS, breast cancer, colon cancer, and prostate cancer. Several of Bavarian Nordic's vaccines are in clinical Phase I and Phase II trials.

13. The smallpox vaccine based on MVA-BN® is identified by its trademark "IMVAMUNE."

14. Bavarian Nordic owns several U.S. patents and pending patent applications directed to MVA-based vaccines. For example, U.S. Patent Nos. 6,761,893 and 6,913,752 cover the MVA-BN® virus and derivatives thereof, IMVAMUNE™, *i.e.*, the smallpox vaccine based on MVA-BN®, and its use as a vector technology.

15. There are ongoing contracts between Bavarian Nordic and the U.S. government to test IMVAMUNE™ through clinical trials. In recognition of its importance to the health of the U.S. population, IMVAMUNE™ is the first smallpox vaccine candidate to be

granted "fast track" status at the Food and Drug Administration ("FDA") for clinical development.

ACAMBIS INC.'S AND ACAMBIS, PLC'S BUSINESS

16. Upon information and belief, Acambis Inc. and Acambis Plc develop and manufacture vaccines to prevent and treat infectious diseases.

17. In September 2000, Acambis received a contract from the U.S. government under which it is currently supplies ACAM2000, which is a smallpox vaccine derived from the same vaccine strain as Dryvax®, *i.e.*, a live virus preparation of vaccinia virus prepared from calf lymph.

18. Upon information and belief, prior to the U.S. government's release of a Request for Proposal for MVA-based smallpox vaccines in September 2002 ("First RFP"), all of Acambis' research and development efforts were focused on smallpox vaccines produced and sold under the tradenames ACAM1000 and ACAM2000. Upon information and belief, prior to the First RFP, Acambis did not actively research or produce a smallpox vaccine based on a weakened form of the MVA strain that would be safe for use in immunocompromised individuals, as well as for the general population.

19. Acambis has partnered with Baxter Healthcare Corporation ("Baxter") to develop a MVA-based smallpox vaccine under two U.S. government contracts. On information and belief, Baxter manufactures or intends to manufacture in Europe, at least in substantial part, the MVA-based vaccine product MVA3000 (also known as ACAM3000), for shipment to Acambis' customers in the United States.

20. While promoting their new vaccine products, Acambis has made false and/or misleading statements to customers and potential customers regarding Acambis' freedom to operate within the field of MVA-based smallpox vaccines.

21. In order to accelerate the development of its own MVA-based vaccine products, Acambis failed to advise its potential customer, the National Institute of Allergy and Infectious Diseases of the National Institutes of Health ("NIAID" and "NIH," respectively) and related governmental agencies that the MVA strains in possession of the government were not available for distribution to Acambis for non-research purposes. This failure to advise amounted to a false representation to the customer of the availability of Bavarian Nordic's proprietary strains.

MVA STRAINS

22. All sources of modified vaccinia Ankara (MVA) originate from Professor Anton Mayr.

23. On or about May 28, 1996, Bavarian Nordic acquired the exclusive license from Professor Mayr for the commercialization of all MVA strains.

24. In January 1994, Professor Mayr deposited MVA-572 in the European Collection of Animal Cell Cultures (ECACC). MVA-572 is the specific passage number 572 of modified vaccinia virus Ankara (MVA) on chicken embryo fibroblast (CEF cells) developed by Professor Mayr.

25. The ECACC prohibits the commercialization of MVA-572, or any derivatives thereof, without express written consent of the individual or organization that

submitted the virus. Other isolates of MVA have also been deposited in the ECACC by either Professor Mayr or Bavarian Nordic.

26. Dr. Bernard Moss of the NIAID requested a sample of MVA-575 from Professor Mayr in 1995, who subsequently provided Dr. Moss with MVA-575.

27. In 2001, Dr. Moss requested an earlier sample of vaccinia virus MVA from Professor Mayr, who again complied with the request, this time providing Dr. Moss with the MVA-572 passage originating from the vaccinia virus MVA developed and passaged by Professor Mayr.

28. Professor Mayr provided Dr. Moss with MVA-575 and MVA-572 on the basis that 1) Dr. Moss was planning to use the strains for expression vector work, 2) the strains were being provided for research only and were not to be used for any commercial purpose without express permission from Professor Mayr; 3) MVA-572 and other isolates of MVA were already deposited into the ECACC with protection against commercialization of the strains without express permission and 4) the strains would not be given by Dr. Moss to anyone or any organization without permission from Professor Mayr.

29. On at least one occasion, a company seeking MVA from NIH and/or NIAID was specifically referred to Professor Mayr for permission to receive a sample of MVA strain from NIH and/or NIAID.

SECRECY AGREEMENTS AND CONFIDENTIAL DISCLOSURE

30. Under a non-disclosure agreement between the Division of Microbiology and Infectious Diseases ("DMID"), NIAID, NIH and Bavarian Nordic executed shortly after

September 11, 2001, Bavarian Nordic disclosed the technology for MVA-BN®, which involves plaque purifying MVA-572 in a manner that attenuates the virus such that it does not replicate in humans. This disclosure led to sponsorship by the NIAID of a pre- Investigational New Drug Application (IND) with Bavarian Nordic during 2002 for IMVAMUNE™.

31. Bavarian Nordic and Acambis entered into a Secrecy Agreement in February 2002 in order to facilitate licensing negotiations between Bavarian Nordic and Acambis with regard to Bavarian Nordic's MVA-BN® technology.

32. Pursuant to this Agreement, Bavarian Nordic personnel explained the technology for MVA-BN® and IMVAMUNE™ to Acambis personnel at a meeting held at Acambis' offices in Boston on June 12, 2002. Thomas Monath, the Chief Scientific Officer of Acambis Plc and Vice President of Acambis Inc. attended the meeting. The clinical data, dosing, and production conditions that were disclosed were the culmination of Bavarian Nordic's extensive research and development efforts dating back to 1996.

33. Following the June 12, 2002 meeting, Acambis requested a licensing proposal, which Bavarian Nordic promptly delivered. The parties negotiated in good faith regarding the licensing terms up to September 2002. However, after the release of the first RFP, Acambis halted all discussions with Bavarian Nordic.

THE FIRST RFP

34. The terrorist attacks of September 11, 2001 in the United States and the anthrax attacks via the U.S. Postal Service resulted in concerns that smallpox could be used as a

weapon of bioterrorism. In response, the U.S. government expressed an interest in stockpiling smallpox vaccines.

35. Bavarian Nordic met with NIAID and/or NIH and Acambis under Non-disclosure and Secrecy agreements, respectively to discuss Bavarian Nordic's innovative MVA based vaccines shortly after September 11, 2001.

36. After its meeting with Bavarian Nordic, NIAID NIH released the first Request for Proposal ("RFP") in September 2002 which outlined the requirements for an attenuated form of the smallpox vaccine virus. In addition, the first RFP indicated that the MVA strain would be supplied to the successful bidder(s).

37. Subsequent to the release of the RFP, both Bavarian Nordic and Professor Mayr attempted to prevent NIAID NIH from releasing MVA-572 to successful applicants under the RFP based on the fact that the virus was originally provided to Dr. Moss for research and not for commercialization into vaccine products.

38. NIAID awarded two, three-year contracts in February 2003 totaling up to $177 million for advanced development of MVA vaccines against smallpox. The contract amount was divided between Bavarian Nordic and Acambis.

39. Upon information and belief, Acambis received MVA-572 or its progeny after the contract award in February 2003 from NIAID NIH.

40. When the first RFP published in September 2002, Bavarian Nordic had already demonstrated efficacy of IMVAMUNE™ in preclinical and clinical studies.

41. Prior to the first RFP, Acambis produced only ACAM1000 and ACAM2000, smallpox vaccines based on non-MVA strains. Upon information and belief, while Acambis was in possession of Bavarian Nordic's proprietary technology regarding MVA-BN® and IMVAMUNE™ prior to the release of the first RFP, they did not possess any of their own technology regarding MVA-based vaccines or the MVA virus. In fact, Acambis only recently initiated Phase I clinical trials in March 2004 of a version of the MVA-based vaccine, *i.e.*, MVA3000, with announced results in April 2005, which was well after the award of the contract related to the first RFP.

42. Bavarian Nordic was given no notice of Acambis' preparation for and entry into the bidding process for the first RFP, even though Acambis and Bavarian Nordic were negotiating licensing of Bavarian Nordic's MVA-BN® and technology related to IMVAMUNE™ and even though Acambis had entered into a non-disclosure agreement with Bavarian Nordic pursuant to which it agreed to use confidential information for evaluation purposes and not for any other purpose.

43. At least as early as June of 2002, Bavarian Nordic had informed Acambis of Bavarian Nordic's exclusive license for the commercialization of all MVA strains.

COUNT I
TORTIOUS CONVERSION

44. Bavarian Nordic incorporates Paragraphs 1 through 43 above by reference.

45. Upon information and belief, Acambis received MVA-572 or its progeny from the NIAID NIH after the First RFP was awarded with knowledge that MVA-572 was Bavarian Nordic's property.

46. Bavarian Nordic has a valid, property interest in MVA-572 and its progeny based on its exclusive license from Professor Mayr for the commercialization of all MVA strains.

47. Acambis had no right to possess MVA-572 and/or its progeny received from NIAID NIH because any delivery to Acambis of MVA-572 or its progeny violated the agreement with Professor Mayr. Acambis was on notice at the time of receiving the virus from NIAID NIH that it did not have a lawful right to receive, possess and exercise control over such MVA-572 virus or its progeny.

48. Bavarian Nordic has been harmed by Acambis' wrongful exercise of possession and control over MVA-572 and/or its progeny in denial of Bavarian Nordic's rights to the strain by Acambis' activity regarding MVA-572 and/or its progeny following the award of part of the NIAID NIH contract based on the First RFP, a subsequent contract award based on a Second RFP, and any ensuing development done on MVA-572 and/or its progeny by Acambis or its contractors.

49. Bavarian Nordic, the owner of exclusive rights in MVA-572, is entitled to the return of MVA-572 and/or its progeny based on its exclusive license from Professor Mayr to commercialize all MVA strains.

50. Bavarian Nordic is also entitled to any damages based on this wrongful exertion of possession, dominion and control that the Court deems proper and just.

COUNT II
MISAPPROPRIATION OF TRADE SECRETS

51. Bavarian Nordic re-alleges and incorporates by reference Paragraphs 1 through 50.

52. At all relevant times, Bavarian Nordic has been in possession of technical and operational trade secrets relating to smallpox vaccines based on an attenuated strain of MVA that fails to replicate in mammalian cells ("Proprietary Technology"). These include, but are not limited to, the production/commercialization process for IMVAMUNE™ and the effective dosing requirements. Some of these trade secrets became public with the issuance of several U.S. patents to Bavarian Nordic.

53. Bavarian Nordic has adopted reasonable measures, including those described herein, to maintain the secrecy of the proprietary technology at issue. For example, Bavarian Nordic obtains non-disclosure agreements before disclosing any of its proprietary technology for bidding or licensing purposes. Bavarian Nordic has invested substantial amounts of money and resources in the development of other safeguards, such as instituting internal company policies and procedures regulating the access to, designation of, and dissemination of its proprietary technology, in order to protect proprietary information relating to how to make and use an attenuated smallpox vaccine based on MVA.

54. The effective dose and production/commercialization process for IMVAMUNE™ have been valuable proprietary property and trade secrets. Bavarian Nordic's proprietary technology derives independent value from not being generally known to the public, or to other persons such as Acambis, who can obtain value from the disclosure thereof or use. As a general matter, these secrets have provided Bavarian Nordic competitive advantages, which

include realizing a return on investment for the time and money expended in arriving at a successful smallpox vaccine for use in immune-compromised individuals as well as for the general population.

55. To the extent that MVA-572 was plaque purified and/or attenuated by NIAID NIH using Bavarian Nordic's proprietary technology relating to MVA-BN® and IMVAMUNE™ prior to delivery of MVA virus to Acambis, Acambis, as a third party receiver, misappropriated, and continues to misappropriate, Bavarian Nordic's proprietary technology by disclosing the proprietary technology to third parties and using the technology to its commercial advantage without Bavarian Nordic's consent in violation of the Delaware Uniform Trade Secrets Act (Del. Code Ann. Tit. 6, § 2001 *et seq.*) and/or other applicable state trade secret misappropriation laws.

56. As set forth above, as a result of its June 12, 2002 meeting with Bavarian Nordic, Acambis was aware that Bavarian Nordic had invested several years of time and money to develop an attenuated MVA strain for use in smallpox vaccines. Based on this knowledge and knowledge of the smallpox vaccine industry, Acambis knew or should have had reason to know that any attenuated MVA strain received from NIAID NIH was provided to Acambis without express or implied consent from Bavarian Nordic.

57. To the extent that MVA-572 was plaque purified and/or attenuated by Acambis after receipt of the strain from NIAID NIH using Bavarian Nordic's proprietary technology relating to MVA-BN® and IMVAMUNE™, Acambis has modified a MVA virus that Acambis had no right to possess or exercise control over based on proprietary information and technology misappropriated from Bavarian Nordic. All such modifications of MVA unlawfully

in the possession of Acambis and such misuse of Bavarian Nordic's proprietary technology to Acambis' commercial advantage without Bavarian Nordic's consent violates the Delaware Uniform Trade Secrets Act (Del. Code Ann. Tit. 6, § 2001 *et seq.*), Delaware common law of misappropriation of trade secrets, and/or other applicable state trade secret misappropriation laws.

58. Acambis knew or had reason to know that any plaque purification and/or attenuation of MVA-572 required adoption and use of Bavarian Nordic's MVA-BN® proprietary technology disclosed to them during the June 12, 2002 meeting. This proprietary technology was acquired by Acambis under circumstances giving rise to a duty to maintain its secrecy and limit its use.

59. Bavarian Nordic has been, and will continue to be, irreparably damaged and harmed by Defendant Acambis Inc.'s and Defendant Acambis Plc's misappropriation, and this damage and harm will continue unless Defendants are enjoined by this Court.

60. Bavarian Nordic is also entitled to damages for the actual loss caused by Acambis' misappropriation of its proprietary technology and/or for any unjust enrichment Acambis has received as a result of its misappropriation.

61. Because Acambis' misappropriation was and is willful and malicious, Bavarian Nordic is entitled to an award of exemplary damages equal to twice its actual damages, as well as reasonable attorneys' fees, in accordance with Sections 2003(b) and 2004 of the Delaware Uniform Trade Secrets Act.

COUNT III
UNFAIR TRADE PRACTICES

62. Bavarian Nordic re-alleges and incorporates by reference Paragraphs 1 through 61.

63. In responding to the First RFP and subsequent RFPs relating to MVA-based smallpox vaccines, Acambis has engaged in deceptive trade practices by passing off MVA3000, Acambis' version of the MVA-based vaccine, as a product of its own research and development, to the NIAID NIH and the smallpox vaccine industry in violation of Delaware's Deceptive Trade Practices Act (Del. Code Ann. Tit. 6 § 2531 *et seq.*), and the Delaware common law of unfair competition. Acambis has further engaged in deceptive trade practices and unfair competition by marketing and using a strain of MVA virus that it has no lawful right to possess or use.

64. As set forth above, upon information and belief, Acambis had never been involved in the development of MVA-based vaccines before Bavarian Nordic shared with Acambis its proprietary technology. Acambis' prior lack of involvement in, or knowledge of, smallpox vaccines based on an attenuated strain of MVA, and the sudden entry of Acambis into direct competition with Bavarian Nordic for the First RFP, make clear that Acambis used the proprietary information it obtained from Bavarian Nordic during the June 12, 2002 meeting and subsequent meetings in order to make MVA3000. Acambis' recent initiation of clinical trials relating the MVA3000 make clear that any "research and development" of the MVA-based vaccine occurred only after the award of the first contract and the receipt of the necessary strain.

65. Bavarian Nordic has been, and will continue to be, irreparably damaged and harmed by Defendant Acambis Inc.'s and Defendant Acambis Plc's unfair trade practices

relating to MVA-based vaccines for smallpox with the NIAID NIH, and this damage and harm will continue unless Defendants are enjoined by this Court.

66. Bavarian Nordic is also entitled to concomitant damages for the actual loss caused by Acambis' unfair trade practice and/or for any unjust enrichment Acambis has received as a result of its unfair trade practice. Because the immediacy of the grievance is not dissipated, an award of treble damages, as well as reasonable attorneys' fees, is within the discretion of the Court.

COUNT IV
UNFAIR COMPETITION UNDER THE LANHAM ACT

67. Bavarian Nordic re-alleges and incorporates herein by reference Paragraphs 1 through 66.

68. The acts of Defendants alleged herein constitute false designation of origin, false or misleading advertising, and/or false or misleading representations of fact under 15 U.S.C. § 1051 *et seq.* and, including, 15 U.S.C. § 1125(a). Such conduct is likely to cause consumers to be confused, mistaken or deceived into believing that Acambis has a right to use Bavarian Nordic's proprietary MVA strains and know how, and/or otherwise believe that Acambis is a legitimate bidder in the RFP process, when in fact they are not. Acambis' actions also may cause consumers to believe that Bavarian Nordic somehow has sponsored or endorsed use of Bavarian Nordic's proprietary strains and know how.

69. Such conduct on the part of Defendants has caused and will continue to cause irreparable injury to Bavarian Nordic, for which Bavarian Nordic has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

A. General damages, restitution and/or disgorgement arising from Acambis' conversion of Bavarian Nordic's property;

B. General damages, restitution and/or disgorgement arising from Acambis' trade secret misappropriation, as well as interest thereon;

C. A return of all MVA virus and its progeny in the possession of Acambis and/or its suppliers to Bavarian Nordic.

D. Exemplary or punitive damages, based upon Acambis' willful and malicious conduct;

E. Attorneys' fees and costs, based on a finding that Acambis has engaged in willful and malicious misappropriation of Bavarian Nordic's proprietary technology;

F. A permanent injunction against Acambis Inc. and Acambis Plc enjoining each of them from incorporating or using Bavarian Nordic's proprietary technology to manufacture, sell, or offer to sell products incorporating, using, or made using Bavarian Nordic's proprietary technology.

G. A permanent injunction against Acambis Inc. and Acambis Plc enjoining each of them from disclosing Bavarian Nordic's proprietary technology.

H. A permanent injunction against Acambis Inc. and Acambis Plc enjoining each of them from passing off MVA3000 or any other MVA-based smallpox vaccine based on an attenuated MVA strain as a product of their own research and development;

I. General damages, restitution and/or disgorgement arising from Acambis' unfair trade practices relating to MVA3000;

J. All other relief that this Court deems just and equitable.

Respectfully Submitted,

Dated: August 19, 2005

John W. Shaw (No. 3362)
D. Fon Muttamura-Walker (No. 4646)
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801
(302) 571-6600
fmuttamara-walker@ycst.com

OF COUNSEL:
Edward A. Pennington
Warren Anthony Fitch
Robert C. Bertin
Stephanie D. Scruggs
George Jones
SWIDLER BERLIN LLP
3000 K Street, N.W.
Suite 300
Washington, D.C. 20007-5116
Phone: (202) 424-7500
Fax: (202) 424-7647

Attorneys for Plaintiff Bavarian Nordic A/S